



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service d20386

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 20 1998

WARNING LETTER

Ref: OC: I1-1797

via FEDERAL EXPRESS

Mr. Bear Hsiung
General Manager
Limate Corporation
3F. No.15, Lane 28
Huan-San Road Section 1,
Nei-Hu, Taipei
TAIWAN

Dear Mr. Hsiung:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products encountered during a review by U. S. Customs Service of a shipment of products manufactured by your firm. These products were laser pointers which are subject to the requirements of 21 CFR 1040.10 and 1040.11. These pointers were being imported by The Imagination Depot, C/O Wendy Armendariz, 1617 Hermosa Ave., Hermosa Beach, California 90254. The following items of noncompliance were observed:

1. 21 CFR 1010.2 Certification: The products failed to have certification labels as required by this section.
2. 21 CFR 1010.3 Identification: The products failed to have identification labels as required by this section.
3. 21 CFR 1040.10(g)(2) Labeling: The products failed to have permanently affixed warning labels such as the Class IIIa warning logotype as required by this section.
4. 21 CFR 1040.10(g)(5) Aperture labels: The products failed to have permanently affixed aperture labels as required by this section.
5. 21 CFR 1040.10(h) User information: The user information supplied with the pointers failed to include a reproduction of the warning labels described in items 3 and 4 above and failed to indicate their respective locations on the pointers.

We understand that these products have been refused entry into the United States. Therefore, we will not require the submission of a notification or a corrective action plan (CAP) for this particular shipment.

However, for any similar non-compliant laser products that may have been imported into the United States, you are hereby advised that Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) requires the submission of notification (21 CFR 1003, 1004) and prohibits any manufacturer from certifying or introducing into commerce or the importation of laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in

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Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter under one of the options listed below. In your response you must also provide the number of the products which have been produced for export to the U.S. and the number of such products that have left the place of manufacturer. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11 and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

A review of our records indicates that we have not received an annual report from your firm for the current reporting period July 1, 1997, to June 30, 1998. This report is required by 21 CFR 1002.11 to be submitted not later than September 1 of each year. Please submit this report at the earliest opportunity.

Based on the noncompliances cited above, it is clear that Limate Corporation, has failed to establish and maintain a quality assurance and testing program that assures compliance of your laser products with the standard. Therefore, by this letter, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration disapproves the quality control and testing program for all laser products produced for or by Limate Corporation. This action is taken under authority of the United States (U.S.) Federal Food, Drug, and Cosmetic Act, Chapter V. Subchapter C - Electronic Products Radiation Control (hereafter referred to as "the ACT").

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the Act, from:

1. Certifying the electronics products manufactured under the disapproved testing program;
2. Introducing or importing products into the United States commerce which bear false or misleading certification, that is, products certified under the testing program which has been disapproved, and
3. Introducing or importing into U.S. commerce any products which do not have a certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic products if it appears that the product fails to comply with the applicable standard, or the manufacturer's testing program has been disapproved.

To resolve this matter, you must submit all information required under 21 CFR 1002.10 so that the CDRH can determine that your company(s) is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

The CDRH will advise you whether your submittal is satisfactory.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, San Francisco District Office, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have further questions on these requirements, please contact Frank W. Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Importer: The Imagination Depot
C/O Wendy Armendariz
1617 Hermosa Ave.
Hermosa Beach, CA 90254